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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,730	12/19/2000	Allan F. Willis	KCX-332 (15927)	5590

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EXAMINER

MAJORINO, ROZ

ART UNIT	PAPER NUMBER
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3763

22

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/741,730

Applicant(s)

WILLIS ET AL

Examiner

Roz Maiorino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7 and 23-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-3, 5-7, 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 lines 13-14 the applicant claims " a durometer less than 10 Shores". In claim 26 lines 7 and 8 the applicant has claimed "durometer of about 50 Shore and a second portion having a durometer of less than about 20 Shore" However the applicant does not indicates which Shore level A-D the valve is. So the examiner has assumed it to be Shore level D because it's a valve and shore level D is very common in trocart valves.

### ***Claim Rejections - 35 USC § 103***

2. Claims 1, 3, 5-7, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.5997503 to Willis et al, and further in view of Patent No.4798594 to Hillsead.

Willis teaches a catheter with distally distending balloon. Willis's apparatus is a gastrostomy catheter which comprises of a valve housing defining an opening having a central axis, the opening extending though the valve housing such that the opening forms part of the fluid path though the medical product. It further contains a valve member disposed within the opening, the valve member having a single seal interface

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defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion towards the central axis, the opposing flexible walls including ends that contract each other along the single seal interface. Willis, however, does not disclose any information regarding the degree of durometers in the material used to make the valve member. Hillstead teaches a medical instrument with a durometer of 30-50 Shore A.

Therefore it could have been obvious to one having ordinary skill in the art at the time the invention was made to combine the two teachings, because by making the valve wall and the valve member from a flexible polymeric material, the valve member can be deformed such that the valve opening can be opened from a closed position when sufficient force is applied to the valve wall to deform the valve member, wherein the valve opening will generally return to the closed position from the open position when the force is no longer applied.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,997,503 to Willis et al in view of U.S. Patent No. 4,798,594 to Hillstead and further in view of U.S. Patent Publication No. 004,9501 to Osbourne et al or U.S. Patent No. 5,720,734 to Copenhaver et al.

Willis in combination with Hillstead teaches a catheter with distally distending balloon. Willis's apparatus is a gastrostomy catheter which comprises of a valve housing defining an opening having a central axis, the opening extending through the valve

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housing such that the opening forms part of the fluid path through the medical product. It further contains a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion towards the central axis, the opposing flexible walls including ends that contract each other along the single seal interface. Willis, however, does not disclose any information regarding the thickness of the valve member, however the idea of using a thickness between 0.002 inches to 0.064 inches is well known in the art, the majority of the valve members are within the thickness mentioned above. Copenhaver and Osbourne are just two examples of apparatus with valve members that use thickness between 0.002 inches to 0.064 inches.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a thickness of 0.004 inches for the thickness of the valve member; because the valve members are used to be opened and closed depending on the exterior force placed on the valve and it is important to have the valve thick enough so it does not tear and thin enough so it does respond to the external force.

***Allowable Subject Matter***

4. Claims 23-27 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

5. Applicant's arguments filed 2-11-2004 have been fully considered but they are not persuasive:

- i.* The applicant has argued that prior art does not teach a durometer of less than 10, however applicant has not indicated what level shore A-D the durometer is refereeing to. Durometer of 10 D is in the same range of durometer of 30A.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RM

  
**BRIAN L. CASLER**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**